SEP 2 7 2000

K002346

Summary of Safety and Effectiveness

Trade Name:

Medtronic AVE *QS 10™ Guidewire.*

Manufacturer:

Medtronic AVE, Inc.
3576 Unocal Street
Santa Rosa, California, 95403

Contact: James E. Machek

Establishment Registration Number: 2953200

Classification Name:

Wire, Guide, Catheter (21 CRF 870.1330)

Device Classification:

QS 10: Class II (21 CFR 870.1330) Panel: Interventional Cardiovascular DCRND

Intended Use and Product Description:

The Medtronic AVE QS 10 Guidewire is indicated for general intravascular use to aid in the selective placement of catheters in the general peripheral, visceral, and cerebral vasculature during diagnostic and/or therapeutic procedures.

The Medtronic AVE QS 10 is a 0.010" stainless steel guidewire with a radiopaque, platinum distal coil. The reshapeable platinum coil has a length of 10cm. The QS 10 Guidewire is coated with a hydrophilic coating except for the proximal 35cm end of the guidewire. The QS 10 Guidewire will be packed individually.

Sterilization, Packaging, and Pyrogenicity:

The QS 10 is packaged in individual dispensing hoops, which are sealed inside their own-labeled foil pouch. The QS 10 Guidewire is created by placing a QS 10 Guidewire sterilized pouch and the IFU in a carton with a QS 10 Label.

The QS 10 is e-beam irradiation sterilized.

Substantial Equivalence:

The Medtronic AVE QS 10 is substantially equivalent to the Micro Therapeutics Inc. (MTI) SilverSpeed™ 0.010" guide wire (K982543)

Establishment of equivalence is based on similarities of intended use, design, and physical characteristics as evaluated by physical bench testing, biocompatibility, and animal studies.

Summary of Safety and Effectiveness:

Safety and effectiveness were evaluated through biocompatibility testing, reliability testing, mechanical testing and animal studies. Testing was conducted on final, sterilized QS 10 Guidewires with guidance in part from "Coronary and Cerebrovascular Guidewire Guidance, January 1995 and PTCA Catheters Atherectomy Catheters Lasers Intravascular Stents," May 1995. The tests were used to assess the mechanical properties of the QS 10 Guidewire. Based on in-vitro and in vivo testing results, Medtronic AVE believes the QS 10 is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2000

Ms. Linda (Linn) Laak
Medtronic AVE, Inc.
c/o Alquest, Inc.
11660 Wayzata Boulevard
Minnetonka, MN 55305-2010

Re: K002346
Medtronic AVE QS 10™ Guidewire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: August 31, 2000
Received: September 1, 2000

Dear Ms. Laak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Page

510(k) Number (if known): K002346

Device Name: Medtronic QS 10 Guidewire

Indications for Use: The Medtronic AVE QS10 Guidewire System is intended for general intravascular use to aid in the selective placement of catheters in the general peripheral, visceral, and cerebral vasculature during diagnostic and/or therapeutic procedures.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K002346

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only